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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,644	02/13/2004	Arnold J. Reuser	24512XY	5388

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,644	REUSER ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/13/2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,40 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26, 40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 26, 40 and 41 are pending and under examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 2.11.01 as follows:

This application is claiming the benefit of prior-filed non-provisional applications No. 09/886,477 filed Jun. 22, 2001, which is a CIP of 09/770,253 filed on Jan. 29, 2001. Copendency between the current application and the prior application is required. The benefit of priority claim based on 09/886,477 is granted. However, 09/770,253, which was abandoned on May 15, 2001, was not copending with 09/886,477. Since these applications were not copending at the time of the filing of the later filed application, the benefit claim to the prior-filed non-provisional application of 09/770,253 has not been granted. Applicant is required to appropriately amend the first sentence(s) of the specification, and the application data sheet, unless applicant can establish copendency between the applications.

Applicant's claim for the benefit of priority to 10/046,180, filed on Jan. 16, 2002, which is a reissue application of 08/700,760 (Jul. 29, 1996; now U.S. Patent 6,118,045) which claims benefit of 60/001,796 (Aug. 2, 1995) has not been granted. It is improper

to claim the benefit of priority to a prior-filed reissue application with a non-provisional application for patent under 35 U.S.C. 111. The court, in *In re* Graff, 111 F.3d 874, 876-77, 42 USPQ2d 1471, 1473 (Fed. Cir. 1997), stated that "[t]he statute does not prohibit divisional or continuation reissue applications, and does not place stricter limitations on such applications when they are presented by reissue, provided of course that the statutory requirements specific to reissue applications are met." Following the decision in Graff, the Office has adopted a policy of treating continuations and divisionals of reissue applications, to the extent possible, in the same manner as continuations and divisionals of non-reissue applications. See M.P.E.P. § 1451. Since the current application is not a divisional or continuation "REISSUE" application, but instead is a utility application, the claim for priority to the previously filed reissue application cannot be granted.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Corven et al. (WO 99/51724; issued on Oct. 14, 1999).

Van Corven et al. teach all the limitations of purity (95, 99 and 99.9% or more), a dosage (at least 5 mg/kg) and a method (intravenous injection) of administration of purified human acid α-glucosidase to patients suffering from lysosomal enzyme deficiency disease. See page 14, lines 8-19 and page 21, lines 13-17. Van Corven et al. also teach the limitation of enzyme taken up by liver and muscle cells of the patient. See page 14, lines 8-19. A holding of anticipation is clearly required.

Claims 26, 40 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Van Bree et al. (WO 00/34451; issued on Jun. 15, 2000)

Van Bree et al. teach the intravenous administration of at least 10 mg/kg up to 40 mg/kg of patient body weight of purified human acid α-glucosidase to patients suffering from Pompe's disease, and that the enzyme will be taken up by liver, heart and muscle cells. See page 18, line 7 through page 19, line 20. Note that the reference also discloses the claimed purity limitation, stating on page 5, lines 22-25, that the most preferred pharmaceutical compositions comprise essentially homogeneous enzyme. See also page 17, lines 23-28, disclosing greater than 95% pure enzyme from transgenic rabbits. A holding of anticipation is clearly required.

Claims 26, 40 and 41 are rejected under 35 U.S.C. 102(a) and 102(e)(2) as being anticipated by Reuser et al. (U.S. Patent 6,118,054; issued on Sep. 12, 2000)

Reuser et al. teach the administration of human acid α-glucosidase to a human patient suffering from Pompe's disease, wherein the enzyme is administered intravenously at about 0.1 to 10 mg/kg of body weight, and wherein the enzyme is purified to homogeneity. See column 12, lines 4-23. See also column 18, lines 38-47. Reuser et al. also disclose purified human α-glucosidase being taken up by muscle cells in a patient. See column 18, claim 17. A holding of anticipation is clearly required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 40 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-20 of U.S. Patent No. 6,118,045. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although they recite a product, the patented claims use terminology indicating an intended use of the product, which is the treatment of a human patient suffering from Pompe's disease by intravenous administration of homogeneous enzyme. A patient suffering from Pompe's disease in the patent is anticipated by a patient deficient in endogenous α-glucosidase in the claims under examination, because Pompe's disease is a synonym for α-glucosidase deficiency disease. The purity of the enzyme, which is 100% pure in the conflicting claims, is an obvious variation of the purity (at least 95%, 99% or 99.9%) in the claims under examination. By properly construing the term "therapeutically effective dosage" by reference to the specification (column 12, lines 20-22), it is clear that such dosages (0.1 – 10 mg/kg) fall within those present in the claims under examination (at least 5 mg/kg).

Portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re* Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). See also M.P.E.P. §804. Therefore, claims 26, 40 and 41 are clearly not patentably distinct from claims 17-20 of U.S. Patent 6,118,045.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Examiner
Art Unit 1651

JEAN C. WITZ
PRIMARY EXAMINER